

Application Serial No. 10/626,178
AMENDMENT C

Attorney Docket No. 3968-088

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DEC 18 2006

This Amendment is responsive to the Office Action mailed July 19, 2006 (hereinafter "Office Action") and is accompanied by a petition for a two-month extension of time along with an authorization to charge the required statutory fee. Claims 17-28 were pending at the time of the Office Action. Claims 17-23 & 25-28 were rejected and claim 24 was allowed. By this Amendment, claims 17, 19, 22, & 28 are amended, claims 26 & 27 are cancelled, and new claims 29-33 are added. No new matter has been added.

Review and reconsideration of the Office Action is respectfully requested in view of the amended claims and the following remarks.

I. AMENDMENTS TO THE CLAIMS**A. CLAIM 17**

Claims 17 – 23 and 26 – 28 stand rejected as anticipated or obvious over three references: Jarboe, Hughes, and Hanke. Jarboe, Hughes, and Hanke disclose families of menthyl ethers. The Applicants have submitted an amendment to Claim 17 that avoids the alleged prior art of Jarboe, Hughes, and Hanke by limiting the claimed compounds to formulations other than menthyl ethers. The new limitation is supported by the Specification, as required by 35 U.S.C. § 112. Care has been taken to avoid introducing new matter. The formulae of paragraphs 0006 and 007 disclose this set of compounds. The Specification discloses compounds wherein X is both 0 and 1 (see, for example, paragraphs 0008, 0021, 0025, 0028, 0067, 0071, and 0072). The specification discloses R³ groups denoting unsubstituted menthyl groups (see paragraphs 0011, 0015, 0024, 0025, 0067, 0068, 0072, and 0077) and denoting other groups (see paragraphs 0011, 0015, 0024, 0025, 0028, 0067, and 0071). One having ordinary skill in the art would recognize from the formulae found in paragraphs 0006 and 0007 that various combinations of R³ groups and X values are disclosed, including those combinations claimed in amended Claim 17.

The Applicants submit that the amendment complies with the requirements of 37 C.F.R. § 1.116, include no new matter, and respectfully request the Examiner enter the amendment.

B. CLAIM 19

Claims 17 – 23 and 26 – 28 stand rejected as anticipated or obvious over three references: Jarboe, Hughes, and Hanke. Jarboe, Hughes, and Hanke disclose families of menthyl ethers. The Applicants have submitted an amendment to Claim 19 that avoids the alleged prior art of

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Jarboe, Hughes, and Hanke by limiting the claimed compounds to formulations other than methyl ethers. Care has been taken to avoid introducing new matter to the claim. The deletion of individual compounds from a list of compounds introduces no new matter, as required by 35 U.S.C. § 112.

C. CLAIM 22

Claims 22 and 23 stand rejected as failing to comply with the written description requirement under 35 U.S.C. § 112 paragraph 1. The rejection states "the original disclosure does not provide support for the newly added limitation 'smokeless'" (Final Action, paragraph 4). The Applicants have submitted an amendment to Claim 22 that deletes the word "smokeless."

D. CLAIMS 26 AND 27

Claims 26 and 27 are now cancelled.

E. CLAIM 29

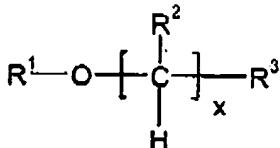
Claim 29 is new. In claiming "The process according to Claim 17, wherein said preparation is administered by chewing, sucking, or eating, and wherein said preparation is selected from the group consisting of: an oral care composition, chewing gum, a food product, a tobacco product, and a pharmaceutical product," the new language avoids the Examiner's reference to Jarboe. Jarboe discloses smoked tobacco products. Care has been taken to avoid introducing new matter. The new claim is limited to methods of administration that are disclosed in the specification (see paragraphs 0002, 0044, 0055, 0056, and 0058). The Applicants submit that one skilled in the art would understand that food products and confectionary products are administered by "eating," although this is not explicitly stated in the Specification.

F. CLAIM 30

New claim 30 is drawn to:

30. (New) A process for creating a clearing feeling in a pharyngeal cavity and nasal cavity and imparting fresh ethereal, minty, sweet and fruit flavor notes in the mouth comprising the step of:

administering to a subject in need thereof an effective amount of a rhinologically active flavoring preparation to be ingested as a solid or a liquid comprising a rhinologically active substance with formula (I):



Formula (I)

wherein

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x is 0 or 1,
 R^1 denotes an alkyl group having 1 to 4 carbon atoms,
 R^2 denotes a methyl or ethyl group, and
 R^3 denotes a monocyclic saturated carbon system having 5,6, 7 or 8 carbon atoms that can be unsubstituted or substituted with further alkyl groups having 1 to 4 carbon atoms or alkenyl groups having 2 to 4 carbon atoms, wherein a clearing feeling in said pharyngeal cavity and nasal cavity is created, wherein said clearing feeling comprises both a cooling feeling and a refreshing feeling, wherein said rhinologically active substance with formula (I) imparts at least one flavor selected from the group consisting of fresh ethereal, minty, sweet, fruity and combinations thereof.

The major distinctions between claim 28 and new claim 30 are underlined for ease of comparison. Of particular interest, claim 30 explicitly recites previously unrecited aspects of the claimed method and add the element that the rhinologically active substance of formula I is used to impart specific flavors.

First, the clearing feeling comprises both a cooling feeling and a refreshing feeling. Support for both feelings can be found throughout the specification, including paragraphs [0002], [0003] & [0018] of the specification. Paragraph [0002] states that "a cooling-refreshing [feeling] and thus a clearing feeling" is produced. This shows that a clearing feeling includes both a cooling feeling and a refreshing feeling. This is noteworthy, since one of ordinary skill in the art would recognize that the refreshing feeling is caused by different receptors than the receptors that cause the cooling feeling.

Second, the preparation that is administered provides not only a clearing feeling but also a flavoring component. In fact, the preparation is a rhinologically active flavor preparation where the rhinologically active substance with formula (I) imparts at least one flavor selected from the group comprising fresh ethereal, minty, sweet, fruity and combinations thereof. Support for this element can be found throughout the specification including paragraphs [0030], [0045] & [0052].

Accordingly, no new matter is presented by new claim 30.

G. CLAIM 31-33

Claims 31 & 32 recite the same elements as canceled claims 26 & 27, respectively.

Claim 33 is drawn to the process of claim 30 with the additional element that the rhinologically active flavor preparation comprises a rhinologically active substance with formula (I) mixed with at least one other flavor substance. Support for a mixture of the rhinologically active substance of formula (I) with a flavor substance can be found throughout the specification

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include paragraphs [0030] & [0036].

Accordingly, no new matter is presented by new claims 31-33.

In compliance with 37 C.F.R. § 116 (b) (2), the Applicants submit the new claim reformulates a previous claim in better form for consideration on appeal, and in compliance with 37 C.F.R. § 116 (b) (1) complies with the Examiner's requirement that the previous claim be supported by the disclosure of the Specification and introduces no new matter. The Applicants respectfully request the Examiner enter the new claim.

II. RESPONSES TO THE FINAL OFFICE ACTION

A. PARAGRAPHS 2 – 4: REJECTIONS OF CLAIMS 22 AND 23 UNDER 35 U.S.C. § 112

Claims 22 and 23 are rejected for failing to comply with the written description requirement of 35 U.S.C. § 112, paragraph 1. The rejection states in paragraph 4: "The original disclosure does not provide support for the new added limitation 'smokeless.'" The rejection is moot because Applicants have amended Claim 22 to omit the limitation of "smokeless." Claim 23 depends on Claim 22, and does not independently recite the limitation of "smokeless." The Applicants believe that claims 22 & 23 are now in proper form for allowance.

B. PARAGRAPHS 5 – 8: REJECTIONS OF CLAIMS 17 – 23 AND 26 – 28 UNDER 35 U.S.C. § 102.

Claims 17 – 23 and 26 – 28 stand rejected under Section 102 (b) over Jarboe (Final Action, paragraph 6), under Section 102 (c) over Hanke (Final Action, paragraph 7), and under Section 102 (e) over Hughes (Final Action, paragraph 8). All three of the cited documents disclose the use of menthol ethers to produce cooling sensations, although the Applicants submit that they do not adequately disclose all of the limitations of the rejected claims. However, the Applicants submit that the amendments to Claims 17, 19 and 28 make the anticipation rejections moot. The three documents are addressed separately below.

1. 102 Rejections Over Jarboe.

Claims 17 – 21, 26 and 27 are rejected over Jarboe. Jarboe discloses the use of menthol ethers to produce a cooling sensation when the user smokes tobacco containing a menthol ether.

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The Applicants traverse the rejection over Jarboe, as Jarboe does not disclose the use of any claimed compound to produce cooling sensations in the pharyngeal cavity or the nasal cavity. The Applicants submit that no evidence exists on the record that the claimed compounds if burned and inhaled will inherently produce cooling sensations in the pharyngeal cavity or the nasal cavity.

However, the rejection over Jarboe is moot in light of the Applicants' amendment to claims 17 and 19, and in light of the Applicants' cancellation of Claims 26 and 27. The compounds disclosed by Jarboe are menthyl ethers. As a result of the Amendments to Claims 17 and 19, these claims no longer claim menthyl ethers. Jarboe does not disclose any compound presently claimed. Therefore, Jarboe cannot anticipate amended Claims 17 and 19. Accordingly, Applicants believe that claim 17 and all claims dependent thereon are drawn to allowable subject matter.

The Applicants respectfully request the Examiner withdraw the rejection and allow the claims.

2. 102 Rejections Over Hanke

Claims 17, 18, 20 – 22, and 28 are rejected over Hanke. The Applicants traverse the rejection, for the following reasons: Hanke does not distinctly point out any claimed compound, and Hanke is not clearly prior art under Section 102 (e) absent evidence as to the Applicants' invention date on the record. However, the Applicants submit that the rejection of the claims as anticipated over Hanke is moot in light of the amendments submitted herein.

Hanke does not disclose any compounds currently claimed in Claims 17, 18, 20 – 22 or 28. Hanke discloses a structure which is a menthyl ether when X is a hydrogen (using the notation of Hanke). As a result of the amendments to Claims 17 and 28, none of the compound limitations in claims 17 & 28 are menthyl ethers. Therefore, Hanke cannot anticipate Claims 17, 19 and 28. Claims 18 and 20 – 22 depend on Claim 17. Accordingly, Applicants believe that claims 17 & 28 and all claims dependent thereon are drawn to allowable subject matter.

3. 102 Rejections Over Hughes

Claims 17, 18, 21 – 22, and 28 are rejected over Hughes. The Applicants traverse the rejection, for the following reasons: Hughes does not distinctly point out any claimed compound, and Hughes is not clearly prior art under Section 102 (e) absent evidence as to the Applicants'

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invention date on the record. However, the Applicants submit that the rejection of the claims as anticipated over Hughes is moot in light of the amendments submitted herein.

Hughes does not disclose any compounds currently claimed in Claims 17, 18, 20 – 22 or 28. Hughes discloses a structure which is a menthyl ether when X is a hydrogen (using the notation of Hughes). As a result of the submitted amendments to Claims 17 and 28, none of the compound limitations in those claims are menthyl ethers. Therefore, Hughes cannot anticipate Claims 17, 19 and 28. Accordingly, Applicants believe that claims 17 & 28 and all claims dependent thereon are drawn to allowable subject matter.

C. PARAGRAPHS 9 – 13: REJECTIONS UNDER 35 U.S.C. § 103

Claims 17 – 22 and 25 – 28 stand rejected as obvious in independent rejections over Hanke, Hughes, and Thomas. The Applicants believe that the amended claims overcome the rejections for the reasons stated below.

1. 103 Rejections Over Hanke and Hughes

Claims 17, 19, 20 and 26 – 27 stand rejected over Hanke or Hughes. The rejection over Hanke states "...the menthyl ether compounds of the instant claims [17, 19, 26 and 27] are clearly suggested by Hanke..." (Final Action, paragraph 11). In light of the current amendments, the rejection is moot. Claims 26 and 27 are cancelled. Amended claims 17 and 19 no longer claim any menthyl ether compounds disclosed by Hanke. Thus, Hanke's suggested menthyl ether compounds do not disclose or suggest the claimed compounds in currently amended claims 17 and 19.

The rejection over Hughes states "...the menthyl ether compounds of the instant claims [17, 19, 20, 26 and 27] are clearly suggested by Hughes..." (Final Action, paragraph 12). In light of the current amendments, the rejection is moot. Claims 26 and 27 are cancelled. Amended claims 17 and 19 no longer claim any menthyl ether compounds disclosed by Hughes. Thus, Hughes's suggested menthyl ether compounds do not suggest the claimed compounds in currently amended claims 17 and 19.

The claimed genus no longer includes menthyl ether compounds. As Hughes and Hanke only disclose menthyl ether compounds, these references do not disclose the claimed genus of compounds. Accordingly, Applicants believe that claims 17 & 28 and all claims dependent thereon are drawn to allowable subject matter.

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2. 103 Rejections Over Thomas

The Examiner rejected Claims 17, 18, 20, 21, 22, 25 and 28 as obvious over U.S. Patent 3,993,604 to Thomas (Final Action, paragraph 13). Thomas discloses a family of compounds not claimed in the instant Application, for a purpose not claimed in the instant Application of enhancing the scent and flavor of a number of products (Thomas, Column 1 lines 10 – 35). As pointed out by the Examiner, if one of the hydrogen atoms bound to the ether carbon was instead a methyl or ethyl group, the resulting compound would fall within the scope of the claims. The Examiner argues that such a chemical modification is obvious.

The Applicants point out that the disclosure of Thomas alone is not sufficient for a *prima facie* showing of obviousness. "The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. *See In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), amended, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." MPEP 2142.

The MPEP § 2142 explains the elements of *prima facie* obviousness: "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

In the instant case, the alleged prior art does not disclose all claim limitations. All of the rejected claims contain the limitation of a step "wherein said clearing feeling in said pharyngeal cavity or said nasal cavity is created" (from independent Claims 17 and 28). As used in the present application, a clearing feeling is a combination of both a cooling feeling and a refreshing

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feeling, see Specification, paragraphs [0002], [0003] & [0018]. This is the critical function of the inventive methods, as evidenced by the Specification (see paragraphs 0001, 0003, 0016 – 0018, 0025, 0026, and 0030). Thomas neither discloses nor suggests the creation of a clearing feeling in the pharyngeal cavity or the nasal cavity. The Applicants have raised this point before, and the Examiner has responded:

This argument is not persuasive because a property need not be described by the prior art in order to anticipate the instant invention. See *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ 2d 1584, 1590 (Fed. Cir. 2004), wherein it is stated that ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment... is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.")

(Final Action, paragraph 25, page 13 – citation from original). The Applicants agree with the Examiner that an inherent property may be cited in an anticipation rejection, as held in *Toro*. However, inherent properties may not be cited in an obviousness rejection for a claimed method.

The distinction between obviousness and inherency is often confused, but the courts have time and again sought to clarify this distinction. "As we pointed out in *In re Adams*, 356 F.2d 998, 53 CCPA, the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *Application of Spornian*, 363 F.2d 444, 448 (CCPA 1966) (emphasis added). "As this court said in *In re Naylor*, 369 F.2d 765, 768, 54 CCPA 902, 905-06, 152 USPQ 106, 108 (1966):(Inherency) is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result." *Application of Shelly*, 566 F.2d 81 (CCPA 1977) (emphasis added – parenthetical from original). "It was here erroneously concluded that: (1) 'the discovery of a use of an inherent quality of a product well known in the art is not patentable because of obviousness...' The conclusion thus disregards the law of the case. Further, it confuses anticipation by inherency, i.e., lack of novelty, with obviousness, which, though anticipation is the epitome of obviousness, are separate and distinct concepts." *Jones v. Hardy*, 727 F.2d 1524, 1529 (Fed. Cir. 1984) (emphasis added). "The district court did not, however, nor does Garlock, apply the Graham criteria, *supra*, to the '390 claims, apparently assuming that the claimed products, having been found inherent in the processes of Sumitomo and Smith, would have been obvious in view of those references. If so, that was error. Inherency and obviousness are distinct concepts." *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 751 F.2d 1540, 1555 (Fed. Cir. 1983) (emphasis added).

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In the instant case, the obviousness rejection is based on the premise that the disclosed use of some of the compounds suggested by Thomas (none of which are claimed in the instant application) would produce the claimed step of creating a clearing feeling. However, as shown by the holding of *Sporman*, "obviousness cannot be predicated on what was unknown." There is no evidence in Thomas that the ability of some compounds to create a clearing feeling was known. In fact, none of the cited references disclose or suggest using any of the claimed compounds to create a refreshing feeling. This limitation is missing from the reference entirely.

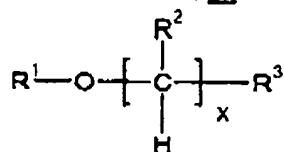
It is undisputed that Thomas does not disclose the use of any compound to produce a clearing feeling, nor does Thomas suggest that related compounds might produce a clearing feeling. Thomas discloses the use of the compounds *related* to those claimed to produce specific smells and flavors, described as spicy, fatty, slightly green, flowery, reminiscent of lily of the valley, animal, reminiscent of castoreum, gustative, woody, fruity, reminiscent of cyclamen, melon-flavored, and apricot-flavored (Thomas, Column 2 line 14 through Column 3 line 14). Although the Specification discusses the potential for the related compounds to possess desirable flavor and odor characteristics, these are not the claimed characteristics. The claimed step requires the creation of a clearing feeling. This may or may not be an inherent property of some compounds suggested by Thomas. But, as explained above, an unknown inherent property cannot render an invention obvious.

III. NEW CLAIMS

New claim 30 is drawn to:

30. (New) A process for creating a clearing feeling in a pharyngeal cavity and nasal cavity and imparting fresh ethereal, minty, sweet and fruit flavor notes in the mouth comprising the step of:

administering to a subject in need thereof an effective amount of a rhinologically active flavoring preparation to be ingested as a solid or a liquid comprising a rhinologically active substance with formula (I):



Formula (I)

wherein

x is 0 or 1,

R^1 denotes an alkyl group having 1 to 4 carbon atoms,

R^2 denotes a methyl or ethyl group, and

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R³ denotes a monocyclic saturated carbon system having 5, 6, 7 or 8 carbon atoms that can be unsubstituted or substituted with further alkyl groups having 1 to 4 carbon atoms or alkenyl groups having 2 to 4 carbon atoms, wherein a clearing feeling in said pharyngeal cavity and nasal cavity is created, wherein said clearing feeling comprises both a cooling feeling and a refreshing feeling, wherein said rhinologically active substance with formula (I) imparts at least one flavor selected from the group consisting of fresh ethereal, minty, sweet, fruity and combinations thereof.

New claim 30 adds two important elements compared with previous independent claim 28. First, the clearing feeling explicitly includes both a cooling feeling and a refreshing feeling. This is critical since one of ordinary skill in the art would recognize that the refreshing feeling is caused by different receptors that the receptors that cause the cooling feeling. Thus, these are distinct features. Second, the rhinologically active flavor preparation provides both a clearing feeling and a flavoring component. In fact, the rhinologically active flavor preparation includes a rhinologically active substance of formula (I) that imparts at least one flavor selected from the group comprising fresh ethereal, minty, sweet, fruity and combinations thereof.

We start with the clearing feeling. This element expressly requires both a cooling feeling and a refreshing feeling. The fact that these are separate features is emphasized by the fact that the cooling feeling and the refreshing feeling are triggered by different receptors in the pharyngeal and nasal cavities. As discussed above, Obviousness cannot be predicated on what is unknown." *Application of Sporman*, 363 F.2d 444, 448 (CCPA 1966) (emphasis added). As noted by the Examiner, both Hughes and Hanke refer to a cooling feeling; however, neither disclose or suggest a refreshing feeling. Clearly, neither Hughes nor Hanke nor any other reference cited by the Examiner, disclose or suggest using the claimed rhinologically active substance with formula (I) as part of a process for achieving the claimed result: a clearing feeling. Accordingly, Applicants believe that claim 30 and all claims dependent thereon are drawn to allowable subject matter.

Second, the preparation that is administered provides both a clearing feeling and, the newly claimed, flavoring component. In fact, the preparation is a rhinologically active flavor preparation where the rhinologically active substance with formula (I) imparts at least one flavor selected from the group comprising fresh ethereal, minty, sweet, fruity and combinations thereof.

Hanke is drawn to a confectionery product and preparation thereof. Hanke teaches that there are significant negative interactions between cooling agents and flavoring agents, but that

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the negative interactions may be reduced by incorporating the cooling agent and the flavoring agent into *separate compositions* in the same product, *see Hanke*, col. 1, ln. 38-45. This core teaching of Hanke draws a clear distinction between cooling agents and flavoring agents. Hanke also teaches that the cooling agents and flavoring agents should be released according to different profiles and goes as far as to prefer embodiments where the cooling agents and flavoring agents are released sequentially, *see Hanke*, col. 7, ln. 49-67.

As discussed above, obviousness cannot be predicated on what is unknown. *Application of Sporman*, 363 F.2d 444, 448 (CCPA 1966) (emphasis added). Clearly, Hanke does not disclose or suggest using cooling agents as flavor agents as in the claimed invention.

Similarly, Hughes provides separate treatment of lipophilic flavorants and physiological cooling agents, *see Hughes*, col. 3, ln. 48-65. A review of Hughes reveals that Hughes teaches that these are two discrete categories of compounds. None of the lipophilic flavorants are listed as physiological cooling agents, or vice versa, *see id.* As discussed above, Obviousness cannot be predicated on what is unknown. *Application of Sporman*, 363 F.2d 444, 448 (CCPA 1966) (emphasis added). Clearly, Hughes does not disclose or suggest using physiological cooling agents as flavorants.

Applicants believe that Thomas does not render new claim 30 obvious for the same reasons that Applicants believe that Thomas does not render Claim 28 obvious. These arguments are recited above in section II.C.2. Accordingly, Applicants believe that claim 30 and all claims dependent thereon are drawn to allowable subject matter.

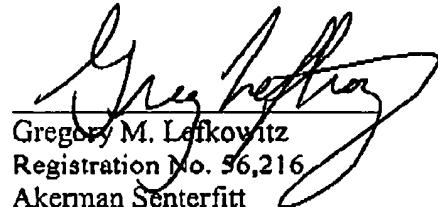
The Commissioner is hereby authorized to charge Deposit Account No. 50-0951 the \$450.00 fee for the necessary retroactive two month extension of time. No additional fees are presently believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 50-0951.

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Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,
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